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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,453	08/31/2005	Cesare Puricelli	206,871	8650

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ABELMAN, FRAYNE & SCHWAB  
10th Floor  
666 Third Ave.  
New York, NY 10017-5621

EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/524,453

Applicant(s)

PURICELLI ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/24/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “knurled external surface of the central body” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6-7, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilmer (Patent No: 4,723,540). Gilmer discloses a titanium bone staple (Figure 2; column 2, lines 65-68) including a “knurled” central body (12; column 3, lines 46-53 and column 4, lines 44-47), two internal threaded parts (14, 16; column 3, lines 1-5), two teeth (20, 30) each having a leg (24, 34) and a threaded end (22, 32), wherein the leg forms a right angle with the threaded end. Gilmer further discloses an apparatus (Figure 5) equipped with a clutch (jaws 46, 47, and 48) to rotate the cylindrical body of the staple (column 4, lines 27-47). The bone staple (10) and the apparatus used to rotate the staple are reasonably understood to comprise a “surgical kit” since Gilmer discloses they are usable together in order to repair bone injuries and disorders.

4. Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkhardt (Patent No. 5,368,596). Burkhardt discloses an instrument (Figure 1) capable of piercing the sternum since it pierces bone (column 4, lines 65-68). The instrument comprises a first jaw (36a) having a punching tip (37a) and a second jaw (36b) having a protuberance (tip 37b) facing the first jaw (36a), wherein a portion of the surface forms an acute angle (surface is slanted) with the axis of the punching tip (37a). Burkhardt

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further discloses handles (18a and 18b) for moving the tip (37a) closer to the second jaw (36b).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmer. Gilmore discloses a device as described above, however, does not disclose the angle between the teeth and legs is between 70 and 85 degrees and that the specific length of the legs is between 10 and 20 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the angle between the teeth and legs between 70 and 85 degrees and form the legs having a length between 10 and 20 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmer in view of Peterson et al. (Publication No. 2004/0059378 A1). Gilmer discloses a device as described above, however, does not disclose the edges of the tip of each leg are rounded. Peterson et al. disclose a fastener for use in wound closures (Figure 1), wherein the edges of the tips (108, 110) of each leg (102, 104) are rounded. It would have been obvious to one of ordinary skill in the art at the time the invention was made to round the edges of the tips on the staple of Gilmer as taught by Peterson et al. in order to be able to effectively retain tissue (paragraph 2) without damaging and scarring tissue (paragraph 9).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burkhart. Burkhart discloses a device as described above, however, does not disclose the angle between a portion of the second jaw and the axis of the punching tip is between 70 and 85 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the angle between a portion of the second jaw and the axis of the punching tip between 70 and 85 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

10. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmer in view of Burkhart. Gilmer discloses a "kit" as described above, however, does not disclose punch cutter forceps. Burkhart discloses an instrument (Figure 1) capable of making holes in a sternum since the instrument pierces bone (column 4, lines 65-68). The instrument comprises a first jaw (36a) having a punching tip (37a) and

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a second jaw (36b) having a protuberance (tip 37b) facing the first jaw (36a), wherein a portion of the surface forms an acute angle (surface is slanted) with the axis of the punching tip (37a). Burkhart further discloses handles (18a and 18b) for moving the tip (37a) closer to the second jaw (36b). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the instrument taught by Burkhart in the surgical kit of Gilmer in order to create a channel for the staple (column 1, lines 9-13).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9:00 a.m. - 6:30 p.m., alternate Fridays 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*  
November 7, 2006

*AN*  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
*11/6/06*